(12) **PATENT APPLICATION** (11) Application No. **AU 200154153 A1**
(19) **AUSTRALIAN PATENT OFFICE**

(54) Title
AV fistula and function enhancing method

(51)[7] International Patent Classification(s)
A61F 002/06

(21) Application No: **200154153** (22) Application Date: **2001.06.29**

(30) Priority Data

(31) Number	(32) Date	(33) Country
09608734	2000.06.30	US

(43) Publication Date : **2002.01.03**
(43) Publication Journal Date : **2002.01.03**

(71) Applicant(s)
Vascular Architects, Inc.

(72) Inventor(s)
Thomas J. Fogarty

(74) Agent/Attorney
SPRUSON and FERGUSON,GPO Box 3898,SYDNEY NSW 2001

The claim defining the invention are as follows:

1. A method for enhancing the function of an AV fistula comprising:

selecting an endoluminal prosthesis comprising a coiled body and a graft material at least partly covering the coiled body to create a coiled stent graft with adjacent turns, said turns having an average width; and

placing the stent graft within an AV fistula and optionally within at least one blood vessel to which the AV fistula is connected.

2. The method according to claim 1 wherein the placing step is carried out with the stent graft placed within the AV fistula and at least one blood vessel so the stent graft extends across the junction between the AV fistula and the at least one blood vessel.

3. The method according to claim 2 wherein the selecting and placing steps are carried out so that the adjacent turns of the stent graft at the junction are spaced-apart from one another so as to not block fluid flow through the blood vessel.

4. The method according to claim 2 wherein the selecting and placing steps are carried out so that the adjacent turns of the stent graft at the junction are next to one another so to effectively block fluid flow along the blood vessel on one side of the junction.

5. The method according to claim 1 wherein the placing step is carried out with the stent graft placed within the AV fistula and a vein.

6. A method for enhancing the function of an AV fistula comprising:

selecting an endoluminal prosthesis comprising a coiled body and a graft material at least partly covering the coiled body to create a coiled stent graft with adjacent turns;

placing the stent graft within the AV fistula and the vein so the stent graft extends across the junction between the AV fistula and the vein;

the selecting and placing steps being carried out so that the adjacent turns of the stent graft at the junction are separated by a gap so to not block fluid flow along the vein.

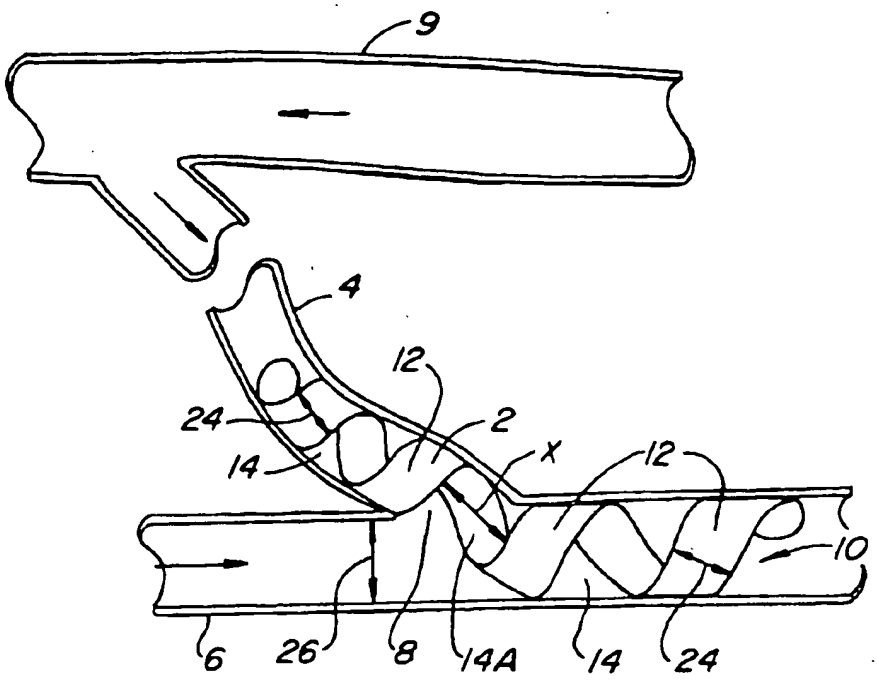

FIG. 1.

FIG. 2.

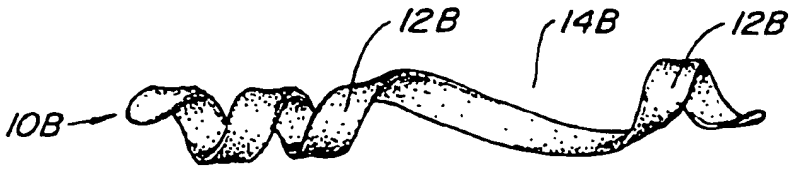

FIG. 3.

the lengths of the gaps varying by more than 100%; and

the stent graft housable partially within the AV fistula and extending past at least one of the venous and arterial ends.

16. A method for enhancing the function of an AV fistula, the method substantially as hereinbefore described with reference to any one of the embodiments shown in the accompanying drawings.

17. An AV fistula assembly substantially as hereinbefore described with reference to any one of the embodiments shown in the accompanying drawings.

Dated 27 June, 2001

Vascular Architects, Inc.

Patent Attorneys for the Applicant/Nominated Person

SPRUSON & FERGUSON

AV FISTULA AND FUNCTION ENHANCING METHOD

BACKGROUND OF THE INVENTION

A fistula is an abnormal passage typically between two organs, such as an artery and a vein. An arterio-venous (AV) fistula is a natural or an artificial graft, typically made of ePTFE (expanded PTFE), between a vein and an artery. An AV fistula, as used herein, also includes naturally-occurring native tissue tubular connections between a vein and an artery. AV fistulas are often used to provide multiple needle access sites for hemodialysis. The AV fistula also helps to increase blood flow through the vein to accommodate the flow rate of blood needed for hemodialysis.

One problem associated with AV fistulas is the progressive narrowing of the AV fistula at the junction with the vein. Such obstructions occur when vascular muscle cells begin growing inwardly causing, for example, thrombosis within the AV fistula. When the thrombus becomes sufficiently large, blood flow decreases and the AV fistula ceases to be effective. It has been found that graft patency after six months is only 66% and that graft failure occurs, on the average, after 18 months.

Improved graft patency has been achieved by the use of vascular clips instead of suturing the AV fistula to the vein. Variations in the angle of implantation have also been shown to affect AV fistula patency. The use of a short length of a PTFE graft has been inserted in the vein to improve patency. (A.S. Coulson, et al., A Combination of the Elephant Trunk Anastomosis Technique and Vascular Clips for Dialysis Grafts, *Surgical Rounds*, 596-608, November 1999.) Also, a PTFE bypass graft to a proximal dilated vein has been used in response to the occurrence of graft-vein stenosis. (Polo, J.R., The State of the Art of Surgical Treatment for Failing Grafts, The Seventh Biannual Symposium on Dialysis Access - Vascular Access for Hemodialysis VII, pp.8-9, May 2000.) Balloon angioplasty and endovascular stents may be used to treat stenosis in AV fistulas (J.E. Aruny, et al., Quality Improvement Guidelines for

FIG. 4.

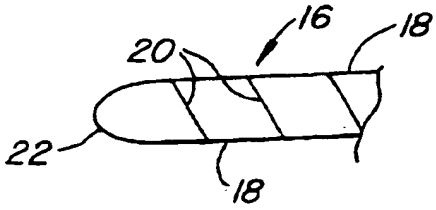

FIG. 5.

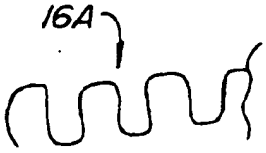

FIG. 6.

Fig. 4 illustrates a further alternative embodiment of the stent graft of Fig. 2 in which the turns are adjacent to one another;

Fig. 5 illustrates the flattened end of the stent graft of Fig. 2 with the graft material removed to illustrate the stent; and

Fig. 6 illustrates an alternative embodiment of the stent of Fig. 5.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

Fig. 1 illustrates the venous end 2 of an AV fistula 4 joined to a vein 6 at a junction 8. The opposite end of AV fistula 4 is connected to an artery 9. The construction of AV fistula 4 and the connections to artery 9 and vein 6 are conventional.

To help treat and/or prevent the obstruction or blockage 6 at junction 8, an endoluminal prosthesis in the form of a coiled stent graft, such as stent graft 10, is placed so that it extends within the venous end 2 of AV fistula 4 and within vein 6 so that stent graft 10 spans both sides of junction 8. Stent graft 10 is typically of a type in which the turns 12 are generally evenly spaced apart from one another by gaps 14. While turns 12 of stent graft 10 may be evenly spaced when in a freely-expanded condition, as in Fig. 2, when placed within fistula 4 and vein 6, the gaps may not be the same from turn to turn. For example, Fig. 1 illustrates the situation in which gap 14A at junction 8 is somewhat larger than the other gaps 14. In some situations it may be desirable to use a stent graft 10A, shown in Fig. 4, in which the turns are adjacent to one another so that even at junction 8, turns 12 would be adjacent or closely spaced to effectively block fluid flow along vein 6 on one side of junction 8, that is the upstream (left) side in Fig. 1.

A typical AV fistula 4 has an inside diameter of about 4-10 mm and a length of about 2-10 cm. Stent graft 10 would typically have a slightly larger freely-expanded outside diameter such as 5 mm for a 4 mm diameter AV fistula. The length of stent graft 10 typically depends upon the length of the AV fistula and whether the stent graft is to extend into one or both of vein 6 and artery 9. Thus, the length of stent graft 10 may range from, for example, 1 cm to over 10 cm.

Instead of the evenly spaced turns 12 of stent graft 10 of Figs. 1 and 2, a stent graft 10B, see Fig. 3, could be used in which an extended gap 14B is provided between to adjacent turns 12B. Stent graft 10B may find particular use with gap 14B positioned at junction 8 to help ensure minimal restriction to fluid flow along vein 6 as well as from AV fistula 4 into vein 6.

AV FISTULA AND FUNCTION ENHANCING METHOD

ABSTRACT OF THE DISCLOSURE

A coiled stent graft (10) is positionable within an AV fistula (4) and optionally into one or both of the artery (9) and the vein (6) to help reduce or eliminate blockages within the blood vessel at the junction (8) between the AV fistula and the blood vessel.

placement catheter, such as one disclosed in U.S. Patent Application No. 09/400,952 filed September 22, 1999, and entitled "Catheter Assembly with Controlled Release Endoluminal Prosthesis". With stent graft 10 tightly wrapped about the placement catheter, the placement catheter is advanced percutaneously into vein 6, and then into venous end 2 of AV fistula 4. Proper longitudinal and rotary placement of stent graft 10 can be monitored using remote visualization techniques, which may or may not involve the use of radiopaque markers carried by the stent graft. Radiopaque markers, when used, would likely be used at the ends of stent graft 10 and/or at the turn or turns 12 expected to be at or adjacent to junction 8 to help ensure proper placement. Once in position, stent graft 10 is released from the placement catheter and is expanded to the position of Fig. 1.

To help eliminate any substantial hindrance to fluid flow along vein 6, stent graft 10 may be selected and placed so that the turns 12 at junction 8 are separated by a distance X. However, future testing may indicate that in some, or possibly all, cases it may be desirable to have turns 12 at junction 8 be positioned adjacent one another to eliminate gap 14A and thus prevent fluid flow through the vein on the upstream (left) side of the junction.

Other modification and variation can be made to the disclosed embodiments without departing from the subject of the invention as defined in the following claims. For example, stent 10 could be a bifurcated, generally Y-shaped stent graft.

Any and all patents, patent applications and printed publications referred to above are incorporated by reference.

S&F Ref: 561365

AUSTRALIA

PATENTS ACT 1990

COMPLETE SPECIFICATION

FOR A STANDARD PATENT

ORIGINAL

Name and Address of Applicant :	Vascular Architects, Inc. 1830 Bering Drive San Jose California 95112 United States of America
Actual Inventor(s):	Thomas J. Fogarty
Address for Service:	Spruson & Ferguson St Martins Tower,Level 35 31 Market Street Sydney NSW 2000 (CCN 3710000177)
Invention Title:	AV Fistula and Function Enhancing Method

The following statement is a full description of this invention, including the best method of performing it known to me/us:-

7. An AV fistula assembly comprising:

an AV fistula comprising a tubular body having a venous end and arterial end;

a coiled stent graft comprising a coiled body and a graft material at least partially covering the coiled body; and

the stent graft housable at least partially within the AV fistula at at least one of venous and arterial ends.

8. The assembly according to claim 7 wherein the coiled stent graft has turns, said turns having edges, said edges of adjacent turns being adjacent to one another.

9. The assembly according to claim 7 wherein the coiled stent graft has turns spaced-apart by gaps.

10. The assembly according to claim 9 wherein the gaps are generally equal in length.

11. The assembly according to claim 9 wherein the lengths of the gaps vary by more than 100%.

12. The assembly according to claim 7 wherein the coiled body comprises a framework of lateral rails and connectors.

13. The assembly according to claim 7 wherein the graft material is synthetic graft material.

14. The assembly according to claim 13 wherein the synthetic graft material is expanded PTFE.

15. An AV fistula assembly comprising:

an AV fistula comprising a tubular body having a venous end an arterial end;

a coiled stent graft comprising a coiled body and a graft material at least partially covering the coiled body, the turns of the coiled stent graft being spaced-apart by gaps;

the lengths of the gaps varying by more than 100%; and

the stent graft housable partially within the AV fistula and extending past at least one of the venous and arterial ends.

16. A method for enhancing the function of an AV fistula, the method substantially as hereinbefore described with reference to any one of the embodiments shown in the accompanying drawings.

17. An AV fistula assembly substantially as hereinbefore described with reference to any one of the embodiments shown in the accompanying drawings.

Dated 27 June, 2001

Vascular Architects, Inc.

Patent Attorneys for the Applicant/Nominated Person

SPRUSON & FERGUSON

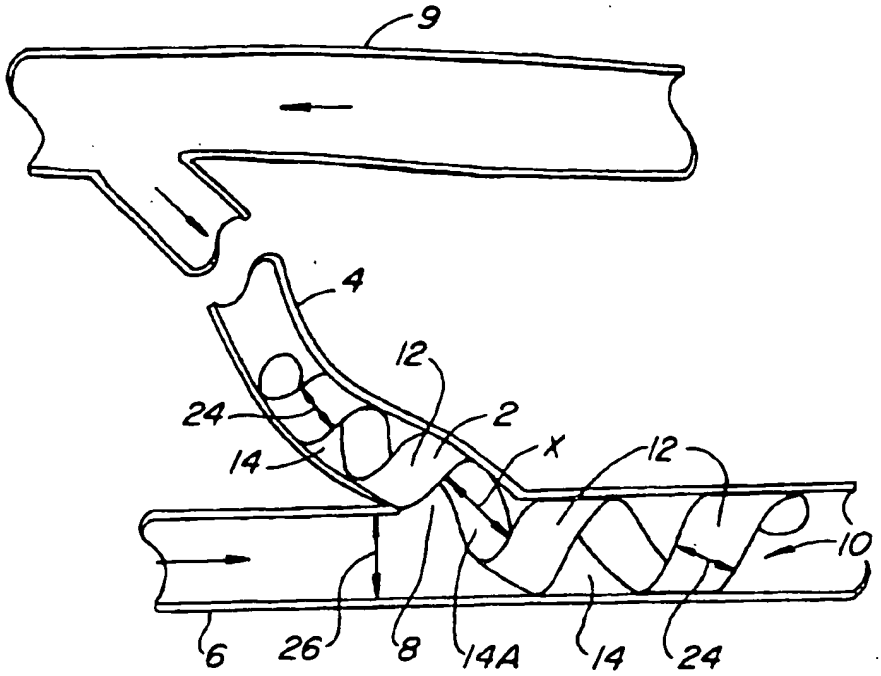

FIG. 1.

FIG. 2.

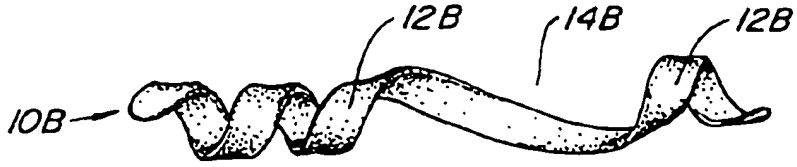

FIG. 3.

FIG. 4.

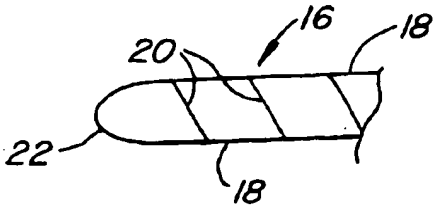

FIG. 5.

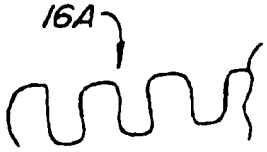

FIG. 6.